

SUMMARY OF THE INVENTION

[0010] Methods and devices are provided for determining a suitable site for sampling physiological fluid. In the subject methods, a potentially suitable physiological sampling site is selected, the fluid flow of the site is characterized and the site is then determined to be suitable based on the whether the site has high or low flow. Suitability may also be determined based on the type of sample obtainable from the site, where the order of the above-described steps may be altered. The subject devices include at least one site flow characterization element for determining the flow characteristics of a potential physiological sampling site and/or at least one sample type characterization element for determining whether the vasculature is arterial, venous or neither, i.e., an interstitial fluid sampling site. The subject methods and devices are particularly suited for use in the detection of physiological sampling sites in the fingers, arms, legs, earlobes, heels, feet, nose and toes. Also provided are kits that include the subject devices for use in practicing the subject methods.

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0011] Figure 1 shows a schematic block diagram representing the subject methods.

[0012] Figure 2 shows a graph of optimal measurements of the subject invention correlated to specific sample type obtainable.

[0013] Figure 3 shows an embodiment of an exemplary device of the subject invention showing a cut-away view of the proximal portion of the device.

[0014] Figure 4 shows an embodiment of an exemplary proximal portion of a device of subject invention.

[0015] Figure 5 shows a graph correlating temperature at a site to the amount of sample expressed therefrom.

DETAILED DESCRIPTION OF THE INVENTION

[0016] Methods and devices are provided for determining a suitable site for sampling physiological fluid. In the subject methods, a potentially suitable physiological sampling site is selected, the fluid flow of the site is characterized and the site is then determined to be suitable based on the whether the site has high or low flow. Suitability may also be

determined based on the type of sample obtainable from the site, where the order of the above-described steps may be altered. The subject devices include at least one site flow characterization element for determining the flow characteristics of a potential physiological sampling site and/or at least one sample type characterization element for determining whether the vasculature is arterial, venous or neither, i.e., an interstitial fluid sampling site. The subject methods and devices are particularly suited for use in the detection of physiological sampling sites in the fingers, arms, legs, earlobes, heels, feet, nose and toes. Also provided are kits that include the subject devices for use in practicing the subject methods. In further describing the subject invention, the subject methods will be described first, followed by a review of the subject devices for use in practicing the subject methods.

[0017] Before the present invention is described, it is to be understood that this invention is not limited to the particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0018] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

[0019] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, the preferred methods and materials are now described.

[0020] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a vessel" includes a plurality of such vessels

and reference to “the device” includes reference to one or more devices and equivalents thereof known to those skilled in the art, and so forth.

[0021] All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

METHODS

[0022] As summarized above, the subject invention provides methods for determining a suitable site for sampling physiological fluid and in some embodiments also provides methods for piercing the skin at the suitable site and further determining the presence and/or concentration of at least one analyte in a sample collected from the site, usually automatically. The subject methods find use in the sampling of a wide variety of physiological fluids, where such physiological fluids include, but are not limited to, interstitial fluids, blood, blood fractions and constituents thereof, and the like. Where the determination of analyte concentration is employed, the subject methods find use in the determination of a wide variety of different analyte concentrations, where representative analytes include glucose, cholesterol, lactate, alcohol, and the like. In many embodiments, the subject methods are employed to determine the glucose concentration in physiological fluid.

[0023] The subject methods determine a suitable sampling site, where suitable sites may be located on various regions of the body, including, but not limited to, the fingers, arms, legs, earlobes, heels, feet, nose and toes. Where, for example, blood is the targeted physiological sample, a potential sampling site is characterized as suitable if the site has a high flow of arterial or venous blood. However, where interstitial fluid or the like is the target physiological sample, a potential sampling site is characterized as suitable if the site has no or substantially no or low amount of arterial or venous blood. Alternatively, the site may be determined to be unsuitable for sampling either blood or interstitial fluid.